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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/658,989	09/10/2003	Jan Bastiaan Bouwstra	BOUWSTRA-3	6068

545 7590 06/24/2005

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EXAMINER	
DESAI, ANAND U	

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 06/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/658,989	BOUWSTRA ET AL.	
	Examiner	Art Unit	
	Anand U. Desai, Ph.D.	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 March 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-28,31 and 32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-28,31 and 32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *20050328*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. This office action is in response to Amendment filed on March 28, 2005. Claims 29-30 have been cancelled. New claims 31-32 have been added. Claims 1-28, 31, and 32 are currently pending and are under examination.

Withdrawal of Rejections

2. The rejection of claim 3 under 35 U.S.C. 112, 2nd paragraph is withdrawn.

3. The rejection of claims 1-4, 6, 9-12, 14, 18, 19, 21, 24, 25, and 27 under 35 U.S.C. 102(a) as being anticipated by Chang, C. et al. (WO 01/34646 A2) is withdrawn.

Maintenance of Rejections

Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1-28, 31, and 32 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-20 of copending Application No. 10/469,747 (U.S. Patent Application Publication 2005/0119170 A1). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the copending application are drawn to a composition suitable as a substance for

plasma comprising a solution of saline in a physiologically acceptable concentration and a recombinant gelatin-like protein having colloid osmotic function comprising a Gly-Xaa-Yaa triplet in which less than 2% of the amino acid residues in the recombinant gelatin-like protein are hydroxyproline residues, and the use of a recombinant gelatin-like protein as a plasma expander. Therefore, it would have been obvious to the person having ordinary skill in the art to describe the currently claimed composition as is being claimed in the copending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 5, 7, 13, 20, and 22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. In claims 5, 13, and 20, there is no particular sequence disclosed that one could determine the positively, and negatively charged amino acids.

9. In claims 7, and 22, there is no particular sequence disclosed that one could determine the location of replacement of glutamine by glutamic acid and/or replacement of asparagines by aspartic acid.

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-7, 9-14, 18-22, 24-27, and 31-32 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The Court of Appeals for the Federal Circuit has recently held that a "written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as be structure, formula [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." *University of California v. Eli Lilly and Co.*, 1997 U.S. App. LEXIS 18221, at *23, quoting *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) (bracketed material in original).

The claims are drawn to gelatin-like proteins, which are not sufficiently described that one of ordinary skill in the art would clearly distinguish the genus from others. To satisfy the written description requirement, the specification must describe the invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. The specification does not describe the structure, that is amino acids in the various polypeptides that can be altered without affecting the colloid osmotic function of a specific polypeptide. For one to be in possession of the claimed invention, the inventor would have to know the functional consequences of structural alterations. Thus due to the limited predictability

in the art, a skilled artisan would not find adequate support for gelatin-like proteins as disclosed in claim 1 in the specification. Suggest describing the gelatin-like protein as in claims 8, 15, 16, 17, 23, and 28 that disclose the structural amino acid sequence of recombinant gelatin-like protein with SEQ ID NO:'s, which retain the colloid osmotic function.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

13. Claims 1-28, 31, and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chang, C. et al. (WO 01/34646 A2) in view of Olsen et al. U.S. 6,413,742 B1. Chang, C. et al. disclose a composition comprising recombinant gelatin having a molecular weight range from about 0 to 50 kDa. Chang, C. et al. disclose a plasma expander comprising recombinant gelatin, and a colloidal volume replacement material comprising recombinant gelatin. Chang, C. et al.

discloses the ability to produce recombinant gelatin with desired isoelectric profile, pH, degree of hydroxylation, and amino-acid compositions (see page 7, line 36 – page 8, line 10, page 28, lines 34-36, page 35, lines 29-37, page 58, lines 5-10, and claims 3, 56, and 57). Chang, C. et al. does not disclose the recombinant gelatin-like protein comprising SEQ ID NO: 1.

Olsen et al. discloses a method to produce recombinant human type I collagen proteins. The method can be used to make any fibrillar collagen, as well as the corresponding types of gelatin for use in medical applications (see U.S. Patent '742, column 3, lines 44-55, and column 4, lines 7-36). One would have been motivated to use the recombinant method disclosed by Olsen et al. to produce a gelatin composition that would have no risk of contaminates such as bovine spongiform encephalopathy (BSE), or Creutzfeldt-Jakob disease.

Therefore, it would have been obvious to a person having ordinary skill in the art to use the method of Olsen et al. to produce a recombinant gelatin protein with the desired isoelectric profile, and amino acid composition as disclosed in Chang, C. et al. to produce a composition suitable as a substitute for plasma substitute, comprising a modified collagen polypeptide (current application, claims 1-28, 31, and 32).

Response to Remarks

Applicant states that Chang, C. et al. does not disclose a recombinant protein plasma expander meeting Applicant's claim requirements having a molecular weight of from at least 10,000 Daltons to at most 50,000 Daltons, and an isoelectric point of less than 8. Applicant's state that Chang, C. et al. generalized disclosure is silent to the specific features of isoelectric point, molecular weight, and freedom from crosslinking of the recombinant gelatin-like protein.

Applicants further state that Chang, C. et al. as a singular disclosure does not meet Applicant's claim requirements. Applicant further states that Olsen et al. does not remedy the deficiencies of Chang, C. et al. Applicant states that nothing in Olsen et al. would assist one skilled in the art to determine what features of a recombinant gelatin protein might render the protein useful as a plasma substitute. Applicant's arguments filed March 28, 2005 have been fully considered but they are not persuasive. Chang, C. et al. does disclose a recombinant gelatin having a molecular weight range of about 0 to 50 kDa (see WO 01/34646, claim 3). Further, Chang, C. et al. disclose a plasma expander comprising recombinant gelatin, and a colloidal volume replacement material comprising recombinant gelatin (see citation in 103 rejection). Olsen et al. disclose the recombinant gelatin-like protein that is deficient in Chang, C. et al.

It would have been obvious to the person having ordinary skill in the art to use a gelatin-like molecule with a molecular size range from 10,000 to 50,000 Daltons, because it was known in the art that plasma substitutes have used modified gelatins in the molecular range of 15,000 to 36,000 Daltons (see Tourtellotte et al. (U.S. Patent 2,827,419, col. 2, line 65 – col. 3, line 3, and claim 20). Furthermore, Nahas, G. et al. (Prog Clin Biol Res. 19: 259-264 (1978)) disclose the use of modified fluid gelatins with molecular weights ranging from 4,000 to 35,000 Daltons (see page 262, Table IV). In addition, Nahas, G. et al. describe the physico-chemical characteristics of two modified fluid gelatins that are used as plasma substitutes. The two compositions have the requisite molecular weight ranges and isoelectric points below 8, particularly Hemacel has an isoelectric point of 4.2, and Plasmion has an isoelectric point of 4.6 (see Table IV). Therefore, a person of ordinary skill in the art would have been motivated to use a recombinant gelatin-like protein to reduce the heterogenicity of gelatin products produced by chemical crosslinking, and

clearly would have emulated the physico-chemical features of known plasma substitutes disclosed prior to Chang, C. et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anand U. Desai, Ph.D. whose telephone number is (571) 272-0947. The examiner can normally be reached on Monday - Friday 7:00 a.m. - 3:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber can be reached on (517) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

June 8, 2005

KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER